

quality and purity fell below the standard set forth therein since it did not contain, in each 100 cc., magnesium citrate corresponding to not less than 1.6 grams of magnesium oxide, as provided in the Pharmacopoeia, but contained Epsom salt (magnesium sulfate) corresponding to 1.14 grams of magnesium oxide per 100 cc.; and it possessed $\frac{1}{8}$ of the quantity of citric acid and approximately $\frac{1}{2}$ of the quantity of sucrose required in the Pharmacopoeia for solution of magnesium citrate.

It was alleged to be misbranded in that its labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users.

On October 19, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

954. Adulteration and misbranding of miscellaneous drugs. U. S. v. 223 Cases of Miscellaneous Foods, Drugs, and Cosmetics. Decree of condemnation. Products ordered released under bond for reprocessing and relabeling good portion. (F. D. C. No. 8509. Sample No. 28246-F.)

Some of these products had been water-damaged and others were very old and deteriorated. They included, among other items, proprietary medicines and surgical dressings.

On October 5, 1942, the United States attorney for the Northern District of Georgia filed a libel against 223 cases of miscellaneous foods, drugs, and cosmetics at Atlanta, Ga., alleging that the articles had been shipped on or about September 16, 1942, by Wells and Harris from Norfolk, Va.; and charging that the drug items were adulterated and misbranded.

The drug items were alleged to be adulterated in that water had been mixed therewith so as to reduce their quality.

They were alleged to be misbranded (1) in that the labeling of some of the items contained false and misleading statements regarding the curative or therapeutic effects of the articles; (2) in that some of the items failed to bear labels containing an accurate statement of the quantity of contents of the packages; (3) in that the labels of some of the items did not bear the common or usual name of the active ingredients of the articles; and (4) in that the labeling of some of the items did not bear adequate warnings against use in those pathological conditions wherein their use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users.

The food and cosmetic items were alleged to be adulterated under the provisions of the law applicable to foods and cosmetics as reported in the notices of judgment on foods and on cosmetics.

On October 12, 1942, John W. Harris, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the products were ordered released under bond for segregation and destruction of the unfit portion, and for reprocessing and relabeling of the good portion under the supervision of the Food and Drug Administration.

955. Misbranding of Bi-Sal Tablets. U. S. v. 237 Bottles of Bi-Sal Tablets. Default decree of condemnation and destruction. (F. D. C. No. 9051. Sample No. 37708-F.)

On December 24, 1942, the United States attorney for the Northern District of Illinois filed a libel against 237 bottles of Bi-Sal Tablets at Chicago, Ill., alleging that the article had been shipped on December 3, 1942, in interstate commerce from Cleveland, Ohio, by Oxford Products, Inc.; and charging that it was misbranded.

Analysis showed that the article contained phenolphthalein, extracts of plant drugs, including capsicum (cayenne pepper), bile extract, and an alkaloid-bearing drug, such as nux vomica.

The article was alleged to be misbranded in that the name "Panogestic Enzymes with Bile Salts Compound" was misleading since the article was essentially a laxative and its physiologic effect was due principally to phenolphthalein, which is neither an enzyme nor a bile constituent, but is a coal tar derivative. The article was alleged to be misbranded further (1) in that the statement appearing in its labeling, "This combination is used * * * in certain forms of Gall Bladder and Bile Duct Infections," was false and misleading since the statement represented and suggested that the article was effective in the treatment of certain forms of gall bladder and bile duct infections, whereas it was not an effective

treatment for any form of such infections, but was essentially a laxative; and (2) in that its labeling failed to bear adequate directions for use since the directions appearing in the labeling "2 tablets about 2 hours after Breakfast and 2 tablets at Bedtime" represented and suggested that the article be taken repeatedly, whereas a laxative should not be directed to be taken repeatedly and such representation and suggestion was not corrected by the label statement "To avoid the 'laxative habit' do not take continuously."

On March 29, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

956. Misbranding of My Prescription, and Pink-etts. U. S. v. 23 Packages of My Prescription. Default decree of condemnation and destruction. (F. D. C. No. 8863. Sample No. 19021-F.)

On November 16, 1942, the United States attorney for the District of New Jersey filed a libel against 23 packages, each package containing a bottle of liquid labeled in part "My Prescription" and an envelope containing 3 pills labeled in part "Pink-etts," at Newark, N. J., alleging that the articles had been shipped in interstate commerce on or about October 27, 1942, from Honesdale, Pa., by F. X. Crockenberg; and charging that they were misbranded.

Examination of samples of the articles showed that the "My Prescription" consisted essentially of bismuth and ammonium compounds, including citrates, sugar, gum, ginger, and water, and that the "Pink-etts" contained a laxative plant drug.

The articles were alleged to be misbranded in that the statements appearing in their labeling, (carton and bottle label) "For Your Stomach A Remedy For Stomach Ills * * * Corrective and Digestant, used in the treatment of Gastric and Duodenal Ulcers," (labels for Pink-etts) "For * * * Liver Trouble, Etc.," (circular) "Stomach Disorders and Their Causes Gastric and Duodenal Ulcers Gastritis Indigestion Gas Pains and all Stomach Disorders 'My Prescription' has been successfully used by hundreds of users. * * * We recommend the use of at least three bottles for permanent relief. * * * The story on the following pages gives you some idea as to the symptoms of stomach disorders and how they are treated. In taking 'My Prescription' all that is necessary is to avoid the things that you know are harmful, in order to give the medicine a quicker and better action," and other circular statements discussing stomach ulcer, were false and misleading since such statements represented and suggested that "My Prescription" was effective in the treatment of diseases of the stomach, and that the "Pink-etts Pills" were effective in the treatment of liver trouble and various conditions included in the designation "etc", whereas the articles were not effective for such purposes.

Further misbranding was alleged in that both products were drugs in package form and their labels failed to bear accurate statements of the quantity of the contents contained therein; and in that the "Pink-etts" were fabricated from two or more ingredients and the label failed to bear the common or usual name of each active ingredient, and in that the labeling failed to bear such adequate warnings against use of the article in those pathological conditions wherein its use might be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form as are necessary for the protection of users, since the article was a laxative and its labeling failed to warn that a laxative should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use might result in dependence upon laxatives to move the bowels.

On January 4, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

957. Misbranding of Natur-Pep. U. S. v. 80 Bottles of Natur-Pep. Decree of destruction. (F. D. C. No. 8688. Sample No. 2642-F.)

Examination showed that the article consisted essentially of Epsom salt (30.9 percent), water, small amounts of iron phosphate, sodium and potassium compounds, methenamine, a salicylate, and extracts of plant drugs including a laxative plant drug.

On or about November 9, 1942, the United States attorney for the Western District of Missouri filed a libel against 80 bottles of Natur-Pep at Kansas City, Mo., alleging that the article had been shipped in interstate commerce from Kansas City, Kans., by the Curts-Folse Laboratories; and charging that it was misbranded.